

RECEIVED
REGION 1

2005 DEC -1 PM 12:44

November 24, 2005

Br. 2

Thomas K. Thompson
Medical Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA
19406-1415

RE: Amendment to the Materials License 54-28275-02MD
Request to not apply the Radiation Symbol on the Product Vial

03030793

Dear Mr. Thompson,

Further to your email of November 18, 2005, MDS Nordion is requesting an amendment to our Materials License 54-28275-02MD to be exempt for the need to affix the radiation symbol on the product vials containing Iodine-131, as required by 10 CFR 32.72 (a)(4)(ii).

MDS Nordion manufactures a therapeutic Iodine 131 labelled monoclonal antibody. This radiopharmaceutical is an injectable and must be manufactured under aseptic conditions. As such the radiopharmaceutical is manufactured and dispensed in the product vial under a pharmaceutical Class 100 environment. The empty product vials entering this environment must be clean and sterile and cannot be prelabelled with a paper or Mylar label.

The Iodine I-131 monoclonal antibody product vial label is printed on the clear glass vial with either the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label is printed directly on the product vial due to the aseptic process, which does not allow for the introduction of a paper pre-printed label. The video printer used does not have the capability for a graphic card and therefore cannot print the radiation symbol. Other printers have been investigated however none have been found to fit with the currently validated process in the facility.

138041
NMSS/RGNI MATERIALS-002

The product vial is placed in a radiation shield and as specified in 10 CFR 32.72 4(i) a label will be affixed to the radiation shield. It should be noted that the vial would typically remain in the lead shield at the customer site. The product will be shipped in dry ice to maintain the stability of the radio labelled monoclonal antibody.

Once the product is used at the customer site and the residual vial contents have decayed, the vial can be defaced by drawing a line through the wording with an indelible black marker.

Due to the manufacturing conditions, MDS Nordion is requesting an amendment to the license to allow for an exemption from the need to affix the radiation symbol on the product vial. The caution wording on the product vial with the label on the shielding container should provide sufficient warning as to the present of the radiation hazard without the need for the radiation symbol on the product vial.

If you require additional information, please do not hesitate to contact me by telephone at (613) 592-3400 extension 2421 or by email at marcandre.charette@mdsinc.com.

Sincerely,



Marc-André Charette
International Transport & Nuclear Initiatives
Manager, Regulatory Affairs

Copy to: Peggy Brandt, John Cybulski, Luc Desgagne, Richard Decaire, MDS Nordion

This is to acknowledge the receipt of your letter/application dated

11/24/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 54-29275-02 MID
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 138041.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader